Virginia Regulatory Town Hall

townhall.virginia.gov

Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-50-10 et seq.
Regulation title	Regulations Governing the Practice of Physician Assistants
Action title	Regulatory reform changes
Date this document prepared	3/4/13

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Amendments will revise terminology for consistency with the Code and current usage; add requirements for the practice agreement to include those relating to prescriptive authority; and revise the notification requirements to make them less burdensome.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On February 21, 2013, the Board of Medicine adopted amendments to 18VAC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants by a fast-track action.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
>
> *1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
>
> *2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
>
> *3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
>
> *...*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

Specific authority for regulation of physician assistants is found in:

> ***§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.***
> *A. A physician or a podiatrist licensed under this chapter may apply to the Board to supervise assistants and delegate certain acts which constitute the practice of medicine to the extent and in the manner authorized by the Board. The physician shall provide continuous supervision as required by this section; however, the requirement for physician supervision of assistants shall not be construed as requiring the physical presence of the supervising physician during all times and places of service delivery by assistants. Each team of supervising physician and physician assistant shall identify the relevant physician assistant's scope of practice, including, but not limited to, the delegation of medical tasks as appropriate to the physician assistant's level of competence, the physician assistant's relationship with and access to the supervising physician, and an evaluation process for the physician assistant's performance.*

No licensee shall be allowed to supervise more than six assistants at any one time.
Any professional corporation or partnership of any licensee, any hospital and any commercial enterprise having medical facilities for its employees which are supervised by one or more physicians or podiatrists may employ one or more assistants in accordance with the provisions of this section.
Activities shall be delegated in a manner consistent with sound medical practice and the protection of the health and safety of the patient. Such activities shall be set forth in a written practice supervision agreement between the assistant and the supervising health care provider and may include health care services which are educational, diagnostic, therapeutic, preventive, or include treatment, but shall not include the establishment of a final diagnosis or treatment plan for the patient unless set forth in the written practice supervision agreement. Prescribing or dispensing of drugs may be permitted as provided in § 54.1-2952.1. In addition, a licensee is authorized to delegate and supervise initial and ongoing evaluation and treatment of any patient in a hospital, including its emergency department, when performed under the direction, supervision and control of the supervising licensee. When practicing in a hospital, the assistant shall report any acute or significant finding or change in a patient's clinical status to the supervising physician as soon as circumstances require, and shall record such finding in appropriate institutional records. The assistant shall transfer to a supervising physician the direction of care of a patient in an emergency department who has a life-threatening injury or illness. The supervising physician shall review, prior to the patient's discharge, the services rendered to each patient by a physician assistant in a hospital's emergency department. An assistant who is employed to practice in an emergency department shall be under the supervision of a physician present within the facility.
Further, unless otherwise prohibited by federal law or by hospital bylaws, rules, or policies, nothing in this section shall prohibit any physician assistant who is not employed by the emergency physician or his professional entity from practicing in a hospital emergency department, within the scope of his practice, while under continuous physician supervision as required by this section, whether or not the supervising physician is physically present in the facility. The supervising physician who authorizes such practice by his assistant shall (i) retain exclusive supervisory control of and responsibility for the assistant and (ii) be available at all times for consultation with both the assistant and the emergency department physician. Prior to the patient's discharge from the emergency department, the assistant shall communicate the proposed disposition plan for any patient under his care to both his supervising physician and the emergency department physician. No person shall have control of or supervisory responsibility for any physician assistant who is not employed by the person or the person's business entity.
B. No assistant shall perform any delegated acts except at the direction of the licensee and under his supervision and control. No physician assistant practicing in a hospital shall render care to a patient unless the physician responsible for that patient has signed the protocol, pursuant to regulations of the Board, to act as supervising physician for that assistant. Every licensee, professional corporation or partnership of licensees, hospital or commercial enterprise that employs an assistant shall be fully responsible for the acts of the assistant in the care and treatment of human beings.
C. Notwithstanding the provisions of § 54.1-2956.8:1, a licensed physician assistant who (i) is working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, (ii) has been trained in the proper use of equipment for the purpose of performing radiologic technology procedures consistent with Board regulations, and (iii) has successfully completed the exam administered by the American Registry of Radiologic Technologists for physician assistants for the purpose of performing radiologic technology procedures may use fluoroscopy for guidance of diagnostic and therapeutic procedures.

§ 54.1-2952.1. Prescription of certain controlled substances and devices by licensed physician assistant.
A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title, a licensed physician assistant shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2001, (ii) Schedules IV through VI

controlled substances on and after January 1, 2003, (iii) Schedule III through VI controlled substances on and after July 1, 2004, and (iv) Schedules II through VI controlled substances on and after July 1, 2007.

A licensed physician assistant shall have such prescriptive authority upon the provision to the Board of Medicine of such evidence as it may require that the assistant has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician or podiatrist which provides for the direction and supervision by such licensee of the prescriptive practices of the assistant. Such written agreements shall include the controlled substances the physician assistant is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician or podiatrist providing direction and supervision.

B. It shall be unlawful for the assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensee and the assistant.

C. The Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of physician assistants as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.
The regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued physician assistant competency that may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients; (ii) requirements for periodic site visits by supervising licensees who supervise and direct assistants who provide services at a location other than where the licensee regularly practices; and (iii) a requirement that the assistant disclose to his patients the name, address and telephone number of the supervising licensee and that he is a physician assistant. A separate office for the assistant shall not be established.

D. This section shall not prohibit a licensed physician assistant from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is to update terminology and reduce the burden of notifying the board when there are changes in the employment or supervision of physician assistants. The amendments will not reduce the responsibility of assistants or physicians to their patients and will continue to protect the health and safety of the public.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The action is less restrictive regulation, has been approved by the Advisory Board on Physician Assistants, and has unanimous approval of the Board of Medicine. It will not be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

The only substantive changes are relating to notification requirements for discontinuation of employment or absences of the supervising physician to make them more reasonable and less burdensome.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1) There are no advantages or disadvantages to the public.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

To achieve this less restrictive regulation, there are no alternative methods, other than the promulgation of an amendment to the licensure requirements.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no costs for electronic notifications to the Public Participation Guidelines. There are no on-going expenditures relating amendments to regulations for physician assistants.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that are likely to be affected by these regulations are physician assistants and their supervising physicians.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 2622 licensed physician assistants; the number of supervising physicians is not known.

All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	There are no costs to small businesses or other entities.
Beneficial impact the regulation is designed to produce.	The reporting requirements are less burdensome for supervising physicians who must be absence from their practices.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives.

Periodic review/small business impact review result

If this fast-track regulation is <u>not the result</u> of a periodic review/small business of the regulation, please delete this entire section.

If this fast-track regulation <u>is</u> the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

There were no comments on the Notice of Periodic Review

1) In accordance with the Code of Virginia, the Board is required to promulgate regulations for the licensure of physician assistants, their supervision in accordance with a practice agreement and their prescriptive authority. Therefore, there is a continued need for the regulation.
2) There were no complaints or comments received from the public.

3) The regulation is organized and written similarly to all other chapters promulgated by the Board of Medicine; it appears to be clear and easily understood.
4) The regulation does not overlap with federal or state law, which is not specific about the criteria for licensure or the standards of practice. Grounds for unprofessional conduct in § 54.1-2915, which apply to all regulated entities under the Board, are not repeated in the regulations.
5) The regulation is frequently reviewed for consistency with changes in technology and practice. Accordingly, it has been amended 9 times in the last 10 years.
The economic impact of this regulation is minimal for a licensure scheme. Fees of $135 per biennium are required to maintain a license and do not appear to be burdensome or inhibiting the growth of the profession as there was a growth rate in the number of physician assistants of 20.2% in the last biennium.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions of words and terms used in regulations	Amendments are deletion of the word "Committee" and change in the term "practice agreement" to "protocol." *In 2002, the Advisory Committee on Physician Assistants was changed in the Code to the Advisory Board. The term is not used in current regulations and can be deleted.* *In a separate regulatory action revising the requirement for a physician to see a patient at least every 4th visit, the term "protocol" is changed to the term "practice agreement" for consistency with current usage and with the wording of the Code in §§ 54.1-2952 and 54.1-2952.1. To clarify that the written authorization for prescriptive authority is part of the practice agreement rather than a separate document, it is added to the definition.*

		Throughout the regulation, the term "protocol" is replaced with "practice agreement" or "agreement."
57	Sets out the requirements for discontinuation of employment	An amendment allows *either* the (employing) supervising physician *or* the assistant to inform the board if the PA is going to discontinue working with the physician with whom he has a practice agreement on file.
101	Sets out the requirements for a protocol (practice agreement)	The additional subsections D and E replace rules currently stated in section150, which is being deleted. The changes are identical to changes in the final regulations in action 3385 / 6476. The intent is to include all requirements for a practice agreement in one section. *Currently, the regulations state that a new protocol (practice agreement) must be submitted with the application for reach biennial renewal if there are any changes. In practice, the board does not require a new* practice agreement but does require a *revised* agreement if there are changes in supervision, prescription authority or scope of practice at the time the change occurs.
115	Sets out the responsibilities of the physician assistant	Changes in subsection B will reduce the burden of notifying when a supervising physician must be absent from the practice. The supervising physician is allowed to name one or more alternate supervisors in the practice agreement. Subsection B currently requires the supervisor to notify the board office if he is unable to supervise due to illness, vacation or unexpected absence and must temporarily delegate supervision to another physician. The amended regulation will require a report only in the absence of both the supervisor and the alternate supervising physician. Likewise, notification for a planned absence will only be required in both the supervising physician and the alternate must be gone.
150	Sets out the requirements for a protocol for prescriptive authority for the physician assistant	The section is being repealed and provisions incorporated into section 101, requirements for a practice agreement.